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REDACTED – PUBLIC VERSION

The Honorable Leonard P. Stark
United States District Court
for the District of Delaware
844 North King Street,
Wilmington DE 19801

VIA ELECTRONIC FILING

Re: *MorphoSys AG v. Janssen Biotech, Inc. et al.*, C.A. No. 16-221 (LPS) (CJB)

Dear Chief Judge Stark:

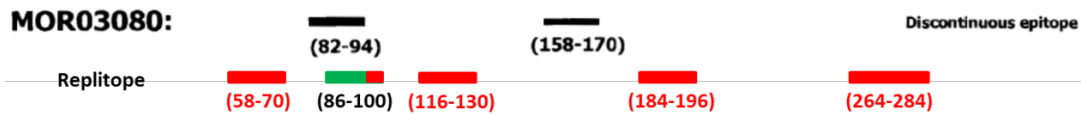
Defendants request leave to amend their answers to include inequitable conduct defenses and counterclaims.

Factual Background. All three patents-in-suit claim antibodies in terms of their binding regions, or “epitopes,” on the target CD38 protein. These claimed epitope ranges are based *entirely* on the specification’s Figure 7—the result of a single October 2003 peptide array epitope mapping study by vendor Jerini (“Jerini Report #3571”). As set forth in Defendants’ Amended Answers (Exs. A and C) however, MorphoSys also commissioned other epitope studies of its anti-CD38 antibodies, which undermine and contradict the data in Figure 7. For example, the “Replitope” study, which mapped the epitope of MOR03080, reported ***binding regions different from the results in Figure 7***. Ex. A ¶¶ 227-37; Ex. C ¶¶ 231-41. Knowing this data eviscerated any basis for its epitope claims, MorphoSys’s deposition witnesses strived to portray the Replitope study as unreliable. But the evidence proves the opposite. For example, contemporaneous documents show that the Replitope study was done in triplicate to ensure reliability, and that Jerini—who had also done the original Figure 7 study—confirmed the results were “evaluable.” Ex. A ¶ 231; Ex C ¶ 235. And MorphoSys likewise treated the Replitope study data as 100% reliable, including it in presentations to its CEO, at conferences, and to actual and potential collaborators. Ex. A ¶¶ 320-35; Ex. C ¶¶ 324-39. As one of many examples, MorphoSys described the Replitope study to collaborator Celgene as “***the*** summary of the MOR3080 epitope mapping.” Ex. A ¶¶ 320-21; Ex. C ¶¶ 324-25. Seemingly, the ***only*** party MorphoSys kept in the dark regarding the conflicting epitope data was the Patent Office. Why? As shown in the graphic below, the Replitope results (shown in color) ***contradict*** the patent’s Figure 7 epitopes (shown in black), undermining Figure 7 and thus eliminating any basis for MorphoSys’s epitope-binding claims. Rather than suffer that consequence, MorphoSys chose to withhold this and other data from the Patent Office.

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This was no accident or innocent mistake. At least four individuals with a duty of candor to the Patent Office knew of the conflicting data and failed to disclose it: (1) lead inventor Michael Tesar; (2) Head of Preclinical Development and Rule 30(b)(6) witness Stefan Steidl; (3) CSO and IP manager Marlies Sproll; and (4) patent attorney Paul Wiegel. Ex. A ¶¶ 277-98; Ex. C. ¶¶ 281-302. A host of produced documents and deposition testimony show that the single most reasonable—indeed the only—inference that can be drawn from the evidence is that MorphoSys intended to deceive the Patent Office. For example, shortly after prosecution started on the '746 Patent, Dr. Sproll warned scientists working on the CD38 project not to perform “further work on the epitope mapping [of] CD38”, so as to “not compromise our already files [sic] patent application!!” Ex. A ¶ 301; Ex. C ¶ 305. Other communications show MorphoSys scientists discussing which sets of epitope data would be used “for the patent.” Ex. A ¶ 340; Ex. C ¶ 344. Yet, instead of disclosing the contradictory data, MorphoSys sought—and obtained—claims based *solely* on the very Figure 7 data it knew to be false.

Legal standard. Federal Rule of Civil Procedure 15(a)(2) provides that a party may amend a pleading with leave of court, and the “court should freely give leave when justice so requires.” Leave to amend should be granted in the absence of undue delay, bad faith, futility, or prejudice to the nonmoving party. *Adams v. Gould*, 739 F.2d 858, 864 (3d Cir. 1984); *Foman v. Davis*, 371 U.S. 178, 182 (1962). Because the deadline to amend pleadings has passed, the party seeking to amend must show good cause. *See* FED. R. CIV. P. 16(b)(4). Where a party could not have met the pleading deadline despite its diligence, good cause is shown. *See Intervet Inc. v. Boehringer Ingelheim Vetmedica, Inc.*, No. 11-595-LPS, 2012 WL 4808427 at *1 (D. Del. Oct. 9, 2012).

Good cause. Recently uncovered facts, including from the February 9, 2018 deposition of MorphoSys’s Rule 30(b)(6) witness Dr. Steidl, support Defendants’ inequitable conduct claims. Due to the heightened pleading requirements, *Exergen Corp. v. Wal-Mart Stores, Inc.*, 575 F.3d 1312, 1318 (Fed. Cir. 2009), and the seriousness of such allegations, Defendants do not plead inequitable conduct lightly and wanted to ensure they took appropriate discovery before doing so. *See, e.g., The Bd. of Trs. of the Leland Stanford Jr. Univ. v. Roche Molecular Sys., Inc.*, No. C 05-04158 MHP, 2008 WL 624771, at *22 n.7 (N.D. Cal. Mar. 4, 2008) (“Waiting to file the motion [to amend for inequitable conduct] until after obtaining corroborating deposition testimony is also sufficient to meet the good cause requirement of Federal Rule of Civil Procedure 16(b).”). The April 5, 2017, deadline to amend pleadings fell two months before substantial completion of document production and over nine months before depositions of MorphoSys’s witnesses (D.I. 115 at ¶¶ 2, 8(b)). The time required to study the numerous documents produced by MorphoSys—some as late as November 15, 2017—and the need to depose Drs. Tesar, Sproll, and Steidl, provide good cause for Defendants’ amendment. And having refused to provide deposition dates before January 2018 (D.I. 213 at n.1), MorphoSys cannot reasonably complain about the timing of this motion. Indeed, this Court has granted leave to amend where (like here), discovery revealed that the patentee “only disclosed a portion of data [to the Patent Office] of which counsel was aware and which [the accused infringer] contends was material,” even though the motion was filed on the last day of fact discovery. *Galderma Labs. Inc. v. Amneal Pharm., LLC*, 2013 WL 5461611, at *1 (D. Del. Sept. 30,

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2013). Defendants bring this motion well before the parties' proposed close of fact discovery (unlike in *Galderma*) and nearly a year before trial (as in *Galderma*).

Good faith basis. Defendants' basis for amendment is set forth in detail in the attached proposed Amended Answers. Ex. A ¶¶ 198-354; Ex. C ¶¶ 202-358. As explained therein, Figure 7 forms the *only* support for the epitope claims in the patents-in-suit, yet MorphoSys knowingly and intentionally withheld other data, including the Replitope study, contradicting Figure 7. Ex. A ¶¶ 348-54; Ex. C ¶¶ 352-58.

No undue delay. As explained above, Defendants were diligent in uncovering the evidence of inequitable conduct. On February 15, 2018, less than a week after deposing Dr. Steidl, Defendants told MorphoSys they intended to add an inequitable conduct claim. On February 28, Defendants sent MorphoSys a proposed amendment, and on March 2, MorphoSys replied that it opposed. The parties met and conferred earlier today, but were unable to reach agreement.

No prejudice. To prove undue prejudice, the non-movant "must show that it was unfairly disadvantaged or deprived of the opportunity to present facts or evidence which it would have offered . . . had the amendments been timely." *ICU Med, Inc. v. RyMed Techs., Inc.*, 674 F. Supp.2d 574, 578 (D. Del. 2009). MorphoSys is not prejudiced because the inequitable conduct claim concerns acts and omissions committed by MorphoSys's own employees, and the facts underlying the claim are in its possession such that it does not need any discovery. In any event, the parties recently proposed a schedule allowing two and a half months of additional fact discovery (D.I. 289), and trial is nearly a year away.

Amendment is not futile. To prevail on a claim of inequitable conduct, the accused infringer must prove that the patentee acted with "specific intent to deceive the PTO." *Therasense, Inc. v. Becton, Dickinson & Co.*, 649 F.3d 1276, 1290 (Fed. Cir. 2011). Because there is rarely direct evidence of deceptive intent, it may be inferred from indirect and circumstantial evidence. *Id.* Defendants' proposed Amended Answers set forth these allegations in full. But the standard for *pleading* inequitable conduct is less rigorous than the standard for *proving* inequitable conduct. As this Court has stated, at the pleading stage, a defendant need only identify "the specific who, what, when, where, and how of the material misrepresentation or omission committed before the PTO." *Cot'n Wash, Inc. v. The Sun Prods. Corp.*, 56 F. Supp. 3d 613, 625 (D. Del. 2014) (quoting *Exergen Corp. v. Wal-Mart Stores, Inc.*, 575 F.3d 1312 (Fed. Cir. 2009)). In determining whether an amendment is futile, the court accepts all pleaded allegations as true and views them in the light most favorable to the moving party. See *Marlowe Patent Holdings LLC v. Dice Elecs., LLC*, 293 F.R.D. 688, 691 (D.N.J. 2013) (citing *Great Western Mining & Mineral Co. v. Fox Rothschild LLP*, 615 F.3d 159, 175 (3d Cir. 2010)). Defendants' proposed Amended Answers set forth all requisite factual allegations, including the "who, what, when, where, and how" and knowledge and intent underlying MorphoSys's inequitable conduct in failing to disclose epitope mapping data contradicting Figure 7 to the Patent Office.

For the foregoing reasons, and the reasons set forth extensively in Defendants' proposed Amended Answers (Exs. A and C), Defendants respectfully request that leave to amend be granted.

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Respectfully,

/s/ Brian P. Egan

Brian P. Egan (#6227)

BPE/dlw

cc: Clerk of Court (Via Hand Delivery)
Counsel of record (Via Electronic Mail)

CERTIFICATE OF SERVICE

I hereby certify that on March 13, 2018, I caused the foregoing to be electronically filed with the Clerk of the Court using CM/ECF, which will send notification of such filing to all registered participants.

I further certify that I caused copies of the foregoing document to be served on March 13, 2018, upon the following in the manner indicated:

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